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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,080	10/28/1999	FRANK J. GONZALEZ	15280-271100	5674

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	23

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/308,080	GONZALEZ ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

--The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

THE REPLY FILED 10 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see attached*.

3. ☒ Applicant's reply has overcome the following rejection(s): *see attached*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *1-11,15-17 and 20-28*.

   Claim(s) withdrawn from consideration: *NONE*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

David J. Steadman

ADVISORY ACTION

1. Claims 1-11, 15-17, and 20-28 are pending in the application.

2. All claims stand finally rejected.

3. The request for reconsideration in the after final amendment of Paper No. 22, filed 12/10/02, is acknowledged. The amendment to the claims would appear to overcome rejections under 35 USC 112, first and second paragraphs as described below. However, the amendment does not place the claims in condition for allowance because the amendment would require further consideration of the claims and require a new search due to newly introduced limitations in the claims. For example, the amendment to claim 1 to limit the human genomic DPD DNA to a DNA comprising nucleotides 432-435 of SEQ ID NO:1 and the amendment to claim 3 to limit the length and position of complementarity of the PCR primer would require the examiner to perform a new search of the prior art as these limitations were not present in claims presented prior to Paper No. 26. Furthermore, a new rejection under 35 USC 112, second paragraph would be required for claim 11 as it is unclear from the claim as to whether the PCR primer of the composition is complementary to or is identical to positions 434-534 of SEQ ID NO:1. See MPEP 714.13 regarding non-entry of after final amendments.

4. In view of the non-entry of the amendment, rejection of claims 1, 3, 8, 10, 11, 15, 20, 22, 24, and 26, under 35 USC 112, second paragraph is maintained. It is noted that the amendment would appear to overcome the rejections. However, in view of the non-entry of the amendment, the rejections are maintained for the reasons of record.

5. In view of the non-entry of the amendment, the written description rejection of claims 1-4, 8-10, 15-17, 20, 22, 24, 26, and 27 under 35 U.S.C. 112, first paragraph, is maintained. The amendment would appear to overcome the rejection of claims 10 and 11. It is noted that the amendment would not appear to overcome the rejection of claims 1-4, 8, 9, 15-17, 20, 22, 24, 26, and 27. Regarding written description of the genus of DPD genes, applicants argue (beginning at page 7 of Paper No. 22) the claims have been amended to recite the sequence of the splice junction comprising the site of mutation at position 434 of SEQ ID NO:1. Applicants argue the claims are not drawn to a genus of DPD genes and

are instead drawn to methods operating upon the genus. Applicants argue the method has been applied to a heterogeneous population of subjects. Applicants argue that even a single species of a recited genus can be sufficient to claim a genus as a whole. Applicants argue that, in accordance with *In re Herschler* (591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979)), the functional description of the claimed methods would lead one of ordinary skill to test the compounds on the genus of DPD genomic DNAs. In view of the non-entry of the amendment, applicants' argument is not found persuasive. It is noted that, even if the amendment were entered, applicants' argument addressing the written description of the DPD gene would not be persuasive. Regarding applicants' argument that the method has been applied to a heterogeneous population of subjects, whether a skilled artisan could make and use the claimed method with any DPD gene based on the disclosure is not at issue. The issue is whether the genus of human genomic DPD genes as recited in the claims has adequate written description in the specification. MPEP 2161 acknowledges that the written description requirement is separate and distinct from the enablement requirement. The description of the functional characteristic of being a human DPD gene and the structural characteristic of comprising a sequence of nucleotides 432-435 of SEQ ID NO:1 and having either G or A at position 434 is insufficient to adequately describe the genus of human DPD genes. It is acknowledged that the claims are not drawn to DPD genes but are instead drawn to methods of using DPD genes for detection of a mutation. Human DPD genomic DNA was not known or conventional at the time of the invention and is an essential feature of the claimed invention and therefore, requires adequate written description. The Federal Circuit (*UC California v. Eli Lilly*, (43 USPQ2d 1398)) has said that a sufficient written description of a genus of DNAs may be achieved by a recitation of a representative number of DNAs defined by nucleotide sequence or a recitation of structural features common to members of the genus, *which features constitute a substantial portion of the genus.* The recited structural features of the genus of recited human DPD genomic DNAs, i.e., comprising a sequence of nucleotides 432-435 of SEQ ID NO:1 and having either G or A at position 434, *does not* constitute a substantial portion of the genus as the remainder of the structure of human DPD genomic DNA is *completely undefined* and therefore encompasses widely variant species of DNAs. Applicants have

disclosed only a single species of human genomic DPD DNA, i.e., SEQ ID NO:1. While a single disclosed species can be sufficient for adequate description, in the instant case the single disclosed species of human genomic DPD DNAs does not provide adequate description. While the cDNA encoding human DPD was known at the time of the invention, the structure of a human genomic DPD DNA was not conventional at the time of the invention. For inventions in an unpredictable art, adequate written description of a genus that embraces widely variant species cannot be achieved by disclosing only one species within the genus. It is noted that in the case of *In re Herschler*, steroids were well known at the time of the invention. It is further noted that *In re Herschler* precedes the current Written Description Guidelines.

Regarding written description of the genus of recited PCR primers of claims 3, 8, 10, and 11, the amendment, to the extent the rejection applies to the recited genus of primers, would appear to overcome the rejection. The specification provides adequate description of the recited primers that are described by their function, i.e., a PCR primer, and structure, i.e., about 15-20 nucleotides in length and complementary to nucleotides 434-861 of SEQ ID NO:1. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record.

6. In view of the non-entry of the amendment, the scope of enablement rejection of claims 4, 9, 17, and 27 is maintained. The amendment would appear to overcome the rejection. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record.

7. In view of applicants' arguments, the rejection of claims 10, 11, 15, and 24 under 35 U.S.C. 103(a) is withdrawn. A reference applied as prior art under 35 USC 102(a) should be disclosed by those other than the inventors. As the only authors of the reference of Gonzales et al. (Trends Pharm Sci 16:325-327) are listed as the sole inventors of the instant application, the reference cannot be applied as prior art under 35 USC 102(a) and the date of the reference precludes application of the reference under 35 USC 102(b). As such, the rejection is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone

are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

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PRIMARY EXAMINER
GROUP ~~1800~~ 1600